DEC 11 2003 K032205 1/2

510(k) SUMMARY

Radiancy (Israel) Ltd.'s Radiancy Acne System with ClearTouch™ Light Unit Assembly

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Manufacturer: Radiancy (Israel) Ltd.

9 Gan Ravve Street

Industrial Park

Yavne Israel

Telephone: 011 972-8-9438010

Facsimile: 011 972-8-9438020

Contact Person: Jonathan S. Kahan, Esq.

Regulatory Counsel

Hogan & Hartson L.L.P.

555 Thirteenth Street, N.W.

Washington, D.C. 20004-1109

Telephone: (202) 637-5794

Facsimile: (202) 637-5910

Email: JSKahan@HHLaw.com

Date Prepared: November 14, 2003

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: Radiancy Acne System with ClearTouch™ Light Unit Assembly

Common Name: Dermatological Laser and Light Unit Assembly

K032205 2/2

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 C.F.R. § 878.4810)

Manufacturing Facility: Radiancy (Israel) Ltd.
9 Gan Ravve Street
Industrial Park
Yavne, Israel

Predicate Devices

ClearLight Phototherapy System, Model CT 420

Intended Use / Indications for Use

The Radiancy Acne System with ClearTouch™ Light Unit Assembly ("Radiancy Acne System") is intended to provide phototherapeutic light to the body. The Radiancy Acne System is generally indicated to treat dermatological conditions. The Radiancy Acne System is specifically indicated to treat mild and moderate inflammatory acne which includes treatment of pustular inflammatory acne in patients with Fitzpatrick skin types I-IV.

Technological Characteristics

The ClearTouch LUA is mounted on the hand piece of Radiancy's SpaTouch Photoepilation System (the "SpaTouch"), or on the hair removal / acne hand piece of Radiancy's SkinStation (the "SkinStation"), in order to treat inflammatory acne (the "Radiancy Acne System"). The Radiancy Acne System consists of two green-coated flash lamps. The Radiancy Acne System produces a wavelength spectrum of 430 – 1100 nm with a pulse duration of 35 msec and has a spot size of 22 x 55 mm.

Substantial Equivalence

The Radiancy Acne System has the same intended use and very similar indications for use, principles of operation, and technological characteristics as the ClearLight Phototherapy System, Model CL 420 ("ClearLight System"). The minor differences between the Radiancy Acne System and the ClearLight System do not raise any new issues of safety and effectiveness. Clinical data demonstrates that the Radiancy Acne System treats mild and moderate inflammatory acne which include pustular inflammatory acne in patients with Fitzpatrick skin types I-IV. Thus, the Radiancy Acne System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2003

Radiancy Ltd.
c/o Mr. Jonathan S. Kahan, Esq.
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington, D.C. 20004

Re: K032205
Trade/Device Name: Radiancy Acne System with ClearTouch™ Light Unit Assembly
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 24, 2003
Received: October 24, 2003

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K032205

Device Name: **Radiancy Acne System with ClearTouch™ Light Unit Assembly**

Indications for Use:

The Radiancy Acne System with ClearTouch Light Unit Assembly ("Radiancy Acne System") is intended to provide phototherapeutic light to the body. The Radiancy Acne System is generally indicated to treat dermatological conditions. The Radiancy Acne System is specifically indicated to treat mild and moderate inflammatory acne which includes pustular inflammatory acne in patients with Fitzpatrick skin types I-IV.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K632205